IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 4 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE
THE OPINIONS AND TESTIMONY OF DUANE PRIDDY, PH.D.

Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (collectively, "Ethicon"), submit this memorandum in support of their motion to exclude the opinions and testimony of Duane Priddy, Ph.D. The cases to which this motion applies are identified in Ex. A.

INTRODUCTION

Plaintiffs designated Dr. Duane Priddy, Ph.D., to offer general causation opinions regarding the alleged oxidative degradation of the Prolene polypropylene in pelvic mesh products manufactured by Ethicon, including TVT, TVT-O, TVT-Secur, TVT Abbrevo, TVT Exact, Gynemesh PS, Prolift, Prolift+M, and Prosima (collectively, "Ethicon mesh products").[1]

In support of his opinions, Dr. Priddy conducted Oxidative-Induction Time ("OIT") testing on ten samples of Prolene taken from pristine Ethicon mesh products in an effort to (i) assess the performance of the antioxidants in Prolene; (ii) predict how long it will take for Prolene to oxidize and degrade; and (iii) evaluate the relative oxidative stability of the Prolene samples. To do so, Dr. Priddy heated the mesh samples to 200° C in an environment of 100%

[1] Ethicon notes that Dr. Priddy expressly acknowledged that he will not offer any opinions regarding alternative design. Ex. D, Priddy 3/8/16 Dep. 131:9-22.

nitrogen that was changed during the testing to 100% oxygen. Dr. Priddy then repeated the OIT testing, although he altered the atmospheric conditions from 100% nitrogen to ambient air.

After the OIT testing was complete, Dr. Priddy extracted the antioxidants from the samples using a methylene chloride solvent and sonication, and conducted gas chromatography-mass spectroscopy ("GC/MS") testing at temperatures of over 200° C in an attempt to quantify the relative antioxidant levels among the samples.

Although Ethicon is aware that the Court disagreed with its arguments, Ethicon respectfully submits that the Court should exclude Dr. Priddy's degradation opinions based on his OIT and GC/MS testing as unreliable and irrelevant. Specifically, exclusion of Dr. Priddy's degradation opinions is warranted because his testing (i) has no correlation to the performance of Ethicon mesh products in the human body; (ii) produces uncertain and speculative results; (iii) was not conducted in accordance with a protocol; (iv) was performed without the use of a proper control; and (v) was not validated using statistical analysis.

Without Dr. Priddy's testing, his degradation opinions are only admissible if they are supported by scientific literature. *See Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017). Yet, none of the materials he cites support the notion that Prolene degrades *in vivo*.

This Court has disputed the validity of Ethicon's position that Prolene's chemical composition renders it materially distinct from other forms of polypropylene as "wholly conceived by lawyers, [and] unfounded in science." *See, e.g.*, Mem. Op. and Order (*Daubert* Motion re: Scott A. Guelcher, Ph.D.), No. 2:12-md-02327, at 6-7 (S.D. W. Va. Aug. 31, 2016) [ECF # 2698] (citation omitted). But Plaintiffs' own experts in this litigation acknowledge that Prolene is unique due to its additive package, including antioxidants that retard *in vivo* oxidation.

In *Huskey v. Ethicon*, Plaintiffs' materials science expert—Dr. Scott Guelcher—conceded that Prolene is different from other forms of polypropylene because it contains proprietary additives. Specifically, Dr. Guelcher testified as follows:

> Q. And what makes Prolene Prolene as opposed to simple polypropylene are the additives that you talked about, correct?
>
> A. Yes. The brand name Prolene is defined by the additives that are added to the polypropylene. . . .
>
> Q. And those additives are what makes Prolene different from the other polypropylene medical devices on the market, correct?
>
> A. There are many different grades of polypropylene; Marlex, Prolene, different grades –
>
> The Court: Is that a yes or a no?
>
> The Witness: I'm sorry. Yes.

Ex. B, *Huskey* 8/25/14 Trial Tr. 156:14–18; 157:11–17; *see also* Ex. C, Guelcher 3/23/16 Dep. 87:23-88:9 ("Q. Prolene has as different chemical composition than pure polypropylene, correct? A. Well, the—yeah, the composition's different because it has these additives.").

But Dr. Guelcher is not the only expert for Plaintiffs to make this concession. Indeed, Dr. Priddy's own testimony demonstrates that Prolene's additives distinguish it from polypropylene:

> Q. Doctor, as a materials scientist, would you agree that Prolene has a different chemical composition compared to pure polypropylene? . . . .
>
> A. It's got stabilizers and additives, yes. . . .
>
> Q. Prolene and polypropylene are not identical, are they?
>
> A. Prolene is polypropylene with additives.

Ex. D, Priddy 3/8/16 Dep. 103:21-104:5.

Further, Dr. Jimmy Mays testified that Prolene's additive package distinguishes it from pure polypropylene and other forms of commercial polypropylene. Specifically, he testfied:

> Q. Is it your testimony that polypropylene and Prolene are chemically different or chemically the same?
>
> A. Prolene is a particular formulation of polypropylene.
>
> Q. So they're chemically different; correct?
>
> A. There are additives added.
>
> Q. But they are chemically different? Polypropylene is chemically different than Prolene; correct?
>
> A. Well, Marlex versus Prolene, the base polymer in both is isotactic polypropylene. There may be different additives in there. There may be different molecular weights of polypropylene use[d]. There may be different molecular weight distributions of the polypropylene that's used. So Prolene is a particular formulation of polypropylene.

Ex. E, Mays 3/2/16 Dep. 30:9-24.

Given that Plaintiffs' experts have testified that Prolene's chemical formulation renders it different from other forms of polypropylene—including other commercially available forms—it simply cannot be said that Ethicon's position is merely the invention of Ethicon's lawyers.

As Dr. Priddy's opinions are unsupported by reliable testing or scientific literature regarding Prolene, the Court should exclude his degradation opinions.

In addition, Dr. Priddy offers various opinions regarding Ethicon's knowledge, state of mind, and corporate conduct. He also seeks to opine about clinical complications allegedly caused by the oxidative degradation of the Prolene in Ethicon mesh products. But Dr. Priddy is not qualified to offer such opinions, which the Court should exclude on that basis.

ARGUMENT

I. Legal Standard

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at **1–3, (S.D. W. Va. July 8, 2014).

II. Dr. Priddy's OIT Testing Is Unreliable and Irrelevant.

Although Ethicon is aware that the Court disagrees with its arguments, Ethicon respectfully submits that Dr. Priddy's opinions based on his OIT testing should be excluded as unreliable and irrelevant.

Dr. Priddy seeks to base his degradation opinions on OIT testing he performed on ten Ethicon mesh exemplars. *See* Ex. F, Priddy Report at 3–4, 11–13. He conducted OIT testing to "compare the relative thermal oxidative stability" of the samples, and to "evaluate the performance of the antioxidant stabilizer in the Ethicon mesh samples and to predict the approximate time to oxidative degradation of the meshes[.]" *Id.* at 3.[2] Dr. Priddy opined that "[b]ecause the degradation science of [polypropylene] has been well known for over 40 years, and the availability of accelerated laboratory aging technology allowing rapid assessment of the rate of material degradation, it is clear that Ethicon meshes manufactured using [polypropylene] cannot survive long term use as a reinforcing medical implant." *Id.* at 3–4.

Dr. Priddy then sought to correlate the level of antioxidants in the mesh samples with his OIT test results using GC/MS. *Id.* at 13. To do so, after the completion of the OIT testing, Dr. Priddy directed Steve Johnson—a lab technician—to extract the antioxidants present in the samples using "methylene chloride solvent" and sonication. *Id.* Mr. Johnson then analyzed the extracts using GC/MS to identify the relative amounts of antioxidants present in the samples. *Id.* Based on this testing, Dr. Priddy concluded that there was significant variation in the amount of antioxidants in the samples, and this variation correlated with his OIT test results. *Id.*

A. Dr. Priddy's Testing Does Not Replicate the *In Vivo* Environment in Which Ethicon Mesh Products Are Used.

[2] Although Dr. Priddy's Report states that his testing measured the "incipient surface oxidation time (ISOT)," Dr. Priddy admitted that ISOT is not a recognized standard; it came from "nowhere" and is something he made up. Ex. D, Priddy 3/8/16 Dep. 65:18–23; 66:14–67:1.

The Fourth Circuit has explained that expert testimony should be excluded if it is based on product testing conducted under "such different circumstances" from those in which the product was used that the results are largely irrelevant. *Chase v. Gen. Motors Corp.*, 856 F.2d 17, 20-22 (4th Cir. 1988); *see also Arroyo v. Ford Motor Co.*, 59 Fed. App'x 524 (4th Cir. 2003) (affirming exclusion of expert opinion due to "deviation of the testing conditions from those at the time of the accident"); *United States v. Russell*, 971 F.2d 1098, 1106 (4th Cir. 1992) (testing is admissible only if conducted under "substantially similar" conditions to actual conditions).

Indeed, courts routinely exclude expert opinions as irrelevant and unreliable when they are based on product testing that does not replicate the conditions in which the product was used. *See, e.g., In re Mirena IUD Prods. Liab. Litig.*, No. 13-MD-2434, 2016 WL 890251, at **28-29 (S.D.N.Y. Mar. 8, 2016) (excluding expert's opinions regarding an intrauterine device based on "testing conditions that do not reliably replicate the conditions inside a woman's uterus").

Moreover, this Court has repeatedly excluded experts' testing that does not replicate the human physiological environment. *See Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at **12-13 (S.D. W. Va. May 6, 2015) (excluding opinions based on testing at temperatures vastly exceeding body temperature); *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at **8–9 (S.D. W. Va. Sept. 29, 2014) (excluding opinions regarding *in vivo* mesh behavior because his methodology "did not replicate an *in vivo* environment").

1. Dr. Priddy's OIT tests were conducted under conditions vastly different than the human body.

Dr. Priddy's testing should be excluded as unreliable and irrelevant in this case because it bears no relationship to the human body. His OIT testing consisted of heating mesh samples to 200° C, then exposing the samples to different atmospheric conditions: (i) 100% nitrogen that was changed during the test to 100% oxygen; and (ii) 100% nitrogen that was changed to

ambient air. Ex. F, Priddy Report at 12; Ex. D, Priddy 3/8/16 Dep. 36:10–15. Although Dr. Priddy was unable to provide details regarding the methodology used in the GC/MS testing, he testified that "it was [conducted] at over 200 degrees." *Id.* at 91:23–92:10.

Dr. Priddy admitted that these conditions far exceed anything ever encountered in the human body. *Id*. at 46:5–17. Specifically, Dr. Priddy testified that the 200° C temperature used in his testing is equivalent to about 392° F, which is approximately 300° F above normal body temperature. *Id.* at 42:15–21; *see also id.* at 48:16–20 (noting the intended use temperature of Ethicon mesh products is 37° C or 98.6° F). Dr. Priddy conceded that concentrations of 100% nitrogen or 100% oxygen are not found *in vivo*. *Id.* at 46:8–17. Dr. Priddy was also unaware of the concentration of oxidizing species in the human body. *Id.* at 70:14–71:4.

Despite recognizing significant disparities between the testing conditions and the human body, Dr. Priddy made no effort to compare the respective environments. Nor did he conduct any of the real-world testing that he testified is necessary to validate the results of accelerated aging tests. *See id.* at 44:11–17; 58:7–10. Absent a valid correlation to the human body, Dr. Priddy's testing is unreliable. *See In re Mirena*, 2016 WL 890251, at **28-29 (failure to replicate *in vivo* conditions "his methodology and the conclusions he draws from it unreliable.").

2. Dr. Priddy Tested Samples with Different Physical Structures and Properties than the Prolene Used in Ethicon Mesh Products.

By testing at 200° C, Dr. Priddy ran tests on mesh samples with radically different structures and physical properties than the Prolene in Ethicon mesh products. Dr. Priddy admitted that the study he relied on for using heat-aging tests explained that "if temperatures are used which are considerably higher than the ones the material is exposed to under normal circumstances, the danger exists of introducing new degradation reactions." *See* Ex. D, Priddy

3/8/16 Dep. 62:2–16; *see also* Ex. G, E. de la Rie, *Polymer Stabilizers: A Survey with Reference to Possible Applications in the Conservation Field*, 33 Studies in Conservation 9–22 (1988).[3]

As discussed above, although the intended use temperature of Ethicon mesh products is 37° C, Ex. D, Priddy 3/8/16 Dep. 48:16–20, all of Dr. Priddy's tests were conducted at 200° C, Ex. F, Priddy Report at 12. Dr. Priddy also acknowledged that the melting point of Prolene is 165° C, Ex. D, Priddy 3/8/16 Dep. 43:3–4, and that while his OIT testing did not require melted samples, all of his OIT testing was conducted on molten Prolene, *id.* at 34:19–35:3.

Thus, despite knowing that heat-based aging tests could "introduce new degradation reactions"—an issue he failed to investigate—all of Dr. Priddy's tests involved the examination of molten polymers with no effort to show that the molten Prolene behaves the same as the solid-state Prolene used in the human body. Such disparities introduce substantial uncertainties in terms of oxidation and degradation rates that Dr. Priddy made no effort to address.

3. The Court Has Excluded Opinions Based On Similar Testing.

This Court's opinions regarding an expert offering a similar opinion in pelvic mesh litigation are instructive. *See, e.g.*, *Mathison*, 2015 WL 2124991, at **12-13; *Frankum v. Boston Sci. Corp.*, No. 2:12-cv-0904, 2015 WL 1976952, at **14-15 (S.D. W. Va. May 1, 2015). In *Mathison*, Dr. Jimmy Mays sought to opine that the pelvic mesh at issue oxidized and degraded based on his thermogravimetric analysis ("TGA"), a test to examine the thermo-oxidative stability of polymers. *See Mathison*, 2015 WL 2124991, at **12-13. Similar to Dr. Priddy's OIT testing, Dr. May's TGA involved exposing the mesh samples to "temperatures well over 200 degrees Celsius when the human body is only approximately 37 degrees Celsius." *Id.* at *12. Plaintiffs in *Mathison* argued that "TGA is 'not intended to mimic the in vivo environment,' but

[3] Dr. Priddy claimed to account for the de la Rie study by stating that his tests were "only a rough approximation" that "has to be validated with actual real-time studies." *See* Ex. D, Priddy 3/8/16 Dep. 62:20–63:2. But Dr. Priddy admitted that he never conducted those real-time studies to validate his work. *Id.* at 58:7–10.

instead 'is used as a model and provides predictive information that is particularly useful for product lifetime assessments.'" *Id.* (citations omitted).

In excluding Dr. Mays's opinions, the Court found that he "produced certain results while testing polypropylene at very high temperatures," and "then somehow concludes that the same results will occur inside the human body at much lower temperatures, without providing any explanation or support for his opinion." *Id.* at *13 ("Dr. Mays has failed to connect his TGA results to the pertinent inquiry, which is whether the [mesh] degrades inside the human body.").

Dr. Priddy relies on his OIT testing to offer opinions regarding the *in vivo* performance of the antioxidants in Prolene and predict when Prolene will oxidize and degrade in the body. Ex. F, Priddy Report at 3. But the disparity between his test conditions and the human body renders his results irrelevant and misleading to the jury. The Court should exclude any opinions based on the testing. *See id.* at *13; *see also In re Mirena*, 2016 WL 890251, at **28-29.

B. By Its Own Terms, Dr. Priddy's OIT Testing is Unreliable and Speculative as It Relates to Ethicon Mesh Products.

Although Dr. Priddy purportedly followed ASTM 3895 as a test protocol, its provisions demonstrate that Dr. Priddy's testing is unreliable and speculative in this case. Ex. H, ASTM 3895-14.[4] For starters, ASTM 3895 states that it "has the potential to be used as a quality control measure to monitor the stabilization level in formulated resin as received from a supplier, prior to extrusion." *Id.* at § 5.1. Thus, by its own terms, OIT testing using ASTM 3895 is intended to assess the stabilization of polymeric resins before the resin is extruded into fibers—not finished products, and particularly not materials exposed to *in vivo* conditions.

[4] Although Dr. Priddy testified that he likely used an older version of ASTM 3895, he could not identify any differences in the two versions. *See* Ex. D, Priddy 3/8/16 Dep. 27:4–24. Furthermore, a review of the summary of changes in ASTM 3895-14 demonstrates that none of the changes affected any aspect of the protocol addressed in this motion. *See* Ex. H, ASTM 3895-14 at 8.

In addition, Note 3 to ASTM 3895 states that no "definitve relationships [have] been established for comparing OIT values on field samples to those on unused products, hence the use of such values for determining life expectancy is uncertain and subjective." Ex. H, ASTM-3895-14 at 2. In other words, there is no scientifically legitimate relationship between Dr. Priddy's test results and Ethicon mesh products that have been implanted in patients. Indeed, Dr. Priddy admitted at deposition that life expectancy preditions derived from this testing method are "uncertain" and "subjective." *See* Ex. D, Priddy 3/8/16 Dep. 50:23–51:4; 51:14-24.[5]

ASTM 3895's Note 7 explains that the "material composition of the specimen holder can influence the OIT test result significantly[.]" *See* Ex. H, ASTM 3895-14 at 7. Yet, Dr. Priddy admitted at deposition that he did not take any steps to determine whether the specimen holder affected the results of his testing on Prolene. *See* Ex. D, Priddy 3/8/16 Dep. 54:17–55:14. Although Dr. Priddy claimed that such validations had been conducted on "past projects," *id.* at 55:8–14, he conceded that he had never conducted any type of degradation testing or analysis on Prolene prior to this case, *id.* at 114:13–18. Indeed, Dr. Priddy could not even identify the composition of the specimen holder used in his tests. *Id.* at 54:5–9.

Dr. Priddy relied on this testing for his opinions, despite the fact that the protocol itself cautions that OIT measurement "can be misleading." *See* Ex. H, ASTM 3895, Note 2 at 2.[6] The

[5] In addressing Note 3's warning that comparing "field samples" to "unused products" is unreliable, Dr. Priddy testified that the "field sample" in his testing is the "virgin, unused implant," as opposed to a mesh explant. *See* Ex. D, Priddy 3/8/16 Dep. 48:24–49:18. Dr. Priddy's failure to distinguish between pristine and used samples shows that he did not understand Note 3's caution regarding the lack of reliability of life expectancy predictions.

[6] Dr. Priddy's testimony shows that he did not fully understand the significance of Note 2. When pressed at deposition to explain the meaning of "misleading" in the context of Note 2, Dr. Priddy testified that "it would be misleading for me to say that one [polypropylene] is better than the other" if he examined "two different polypropylenes with two different stabilizer packages . . . and I run an OIT and get different values[.]" *See* Ex. D, Priddy 3/8/16 Dep. 45:7–22. Dr. Priddy clearly missed the point of Note 2's warning that OIT testing can be misleading, because Note 4 directly addresses the point Dr. Priddy raised at deposition. *See* Ex.H, ASTM 3895, Note 4 at 2 (explaining that "OIT test is a function of a particular compound's stabilizer system and should be be used as a basis of comparison between formulations that might contain different resins, stabilizers, or additive packages, or all of these.").

Court should not permit Dr. Priddy to offer opinions at trial based on methods that—as described by Dr. Priddy's protocol—can produce "uncertain," "subjective," and "misleading" results.

C. Dr. Priddy Failed to Follow His OIT Testing Protocol.

Although Dr. Priddy claims that he "did not deviate from the protocol listed in" ASTM 3895, *see* Ex. F, Priddy Report at 3, his testimony reveals that he failed to follow the protocol's sample preparation procedures. Section 9 of ASTM 3895 provides a recommended sample preparation procedure in order to ensure "consistent sample morphology and weight." *See* Ex. H, ASTM 3895 § 9.1 at 2. Yet, Dr. Priddy admitted that his test samples were not compressed or molded into a sheet format in accordance with ASTM section 9.1. *See* Ex. D, Priddy 3/8/16 Dep. 36:2–4. Notably, Dr. Priddy failed to record the sample preparation process in his Report, and was unable to identify the average thickness of the samples, (*see id.* at 35:12–36:1; 38:15–21), thereby preventing objective assessment of his methods.

Dr. Priddy did not offer any scientific basis for his deviation from the protocol. He claimed that (i) the sample preparation process was merely "recommended"; (ii) adherence to the process would have "affected the results negatively" by adding another "heat history"; and, (iii) he "wanted to have the samples tested in their original use shape as monofilaments." *Id*. at 36:2–9; 37:16–38:3. But he made no effort to determine what effect, if any, compliance with the sample preparation protocol would have had on his test results. In addition, Dr. Priddy's rationale rings hollow given that all of the samples were molten by the time he analyzed them.

Dr. Priddy's inability to ensure that his samples were uniform highlights the "wide differences" in his test results. As this Court has explained, "[v]igorous adherence to protocols and controls are the hallmarks of 'good science.'" *Sanchez*, 2014 WL 4851989, at *28. Dr.

Priddy's failure to follow his protocol in his testing further evidences the lack of reliability of his opinions. The Court should preclude Dr. Priddy from testifying on this basis.

D. Dr. Priddy Failed to Use a Control in His Testing.

Dr. Priddy and Mr. Johnson's testing is also unreliable because they failed to use proper controls. As an initial matter, nothing in Dr. Priddy's Report or deposition suggests that Mr. Johnson used a control when conducting his OIT testing. For this reason, Dr. Priddy cannot confirm that the methodology used in his OIT testing did not introduce error into his results.

Although Dr. Priddy claims that Mr. Johnson used a control for the GC/MS testing, Dr. Priddy's testimony demonstrates that Mr. Johnson merely used an "internal standard" to determine if the "equipment is operating." *See* Ex. D, Priddy 3/8/16 Dep. 84:2–13. But Dr. Priddy made no effort to control for the effects of his testing methodology.

For example, Dr. Priddy and Mr. Johnson did not perform the removal process on a sample of pure polypropylene—*i.e.*, a sample not containing antioxidants. Thus, Dr. Priddy cannot confirm that the use of methylene chloride and sonication in the extraction process did not introduce error by affecting the polypropylene component of Prolene. Likewise, because they failed to run a sample of pristine Prolene through the extraction process, Dr. Priddy cannot confirm that the prior OIT testing process itself did not confound the GC/MS results. Indeed, Dr. Priddy and Mr. Johnson failed to use such controls even though the GC/MS testing failed to detect one of the antioxidants used in Prolene unless the test conditions were altered. *See* Ex. F, Priddy Report at 8; Ex. D, Priddy 3/8/16 Dep. 87:12–88:14.[7]

[7] Dr. Priddy failed to note in his Report that he and Mr. Johnson ran the test under different conditions; rather, the Report states only that "[m]y testing in this case [GC/MS] did not detect the presense of any [] additive other than Santonox R." *See* Ex. F, Priddy Report at 8. Nor did Dr. Priddy explain if this additional testing under different conditions altered the GC/MS results for the other additives.

Absent such controls, Dr. Priddy cannot determine if there is a rate of error associated with attempting to extract antioxidants by soaking the samples in a methylene chloride solvent and applying sonication. *See, e.g., Cooper v. Smith & Newphew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) ("[W]hether a technique has a high known or potential rate of error and whether there are standards controlling its operation" is a factor guiding a district court's *Daubert* inquiry); *see also Sanchez*, 2014 WL 4851989, at *28.

E. Dr. Priddy Lacks a Sufficient Understanding of His Own Testing.

Dr. Priddy testified that all of the testing on which he bases his opinions was performed by a technician, Mr. Steve Johnson. *See* Ex. D, Priddy 3/8/16 Dep. 81:18–82:12. Although an expert can rely on testing performed by others at his direction, such reliance does not obviate Federal Rule of Evidence 702's requirement that expert testimony consist of "scientific, technical or specialized knowledge" that will assist the trier of fact, and "based upon sufficient facts or data" and "the product of reliable principles and methods" which has been reliably applied "to the facts of the case." *See Edwards*, 2014 WL 3361923, at *1.

In this case, it is not possible to determine whether Dr. Priddy's opinions are consistent with Rule 702 because he was unable to answer numerous questions regarding the methodology employed by Mr. Johnson. For instance, Dr. Priddy failed to provide information in his Report or deposition regarding the sample preparation process for the OIT testing. *See* Ex. D, Priddy 3/8/16 Dep. 35:12–22. He did not know the standard operating procedure he claims Mr. Johnson followed in conducting the GC/MS testing. *Id.* at 82:14–83:5. Dr. Priddy could not identify the samples on which Mr. Johnson performed GC/MS testing. *Id.* at 91:15–22. Nor could Dr. Priddy specify the temperature at which the GC/MS testing was conducted, or the quantity of solvent that Mr. Johnson used in the additive extraction process. *Id.* at 92:6–10; 92:18–21.

At deposition, Dr. Priddy repeatedly deflected questions about the testing by referencing a lab book prepared by Mr. Johnson. *See, e.g.*, Ex. D, Priddy 3/8/16 Dep. 53:3–21; 82:14–83:5; 84:21–85:13; 99:3–22. But Dr. Priddy failed to produce a copy of this lab book to Ethicon.

Given the absence of information regarding the methodology used in his testing—and Dr. Priddy's inability to provide such information—it cannot be said that his opinions are consistent with Rule 702. Accordingly, the Court should preclude Dr. Priddy from testifying at trial.

F. Dr. Priddy Failed to Provide Statistical Analysis of His Test Data.

Dr. Priddy claims that he validated his test results using statistical analyses to correlate the OIT data with the GC/MS data regarding the amount of antioxidants in the mesh samples. *See* Ex. D, Priddy 3/8/16 Dep. 39:21–40:7. Yet, Dr. Priddy's Report contains no such statistical analysis. When pressed to explain his failure to include these alleged statistical analyses in his Report, Dr. Priddy stated merely that he "[j]ust didn't include it." *Id.* at 39:14–20.

Dr. Priddy asks the Court to take his word for it that he conducted statistical analysis on his test results, which validated those test results. But "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

III. The Scientific Literature On Which Dr. Priddy Relies Does Not Support His Degradation Opinions.

A. Dr. Priddy relies on articles that do not assess Prolene.

Because his OIT testing is unreliable and irrelevant, Dr. Priddy's opinion that the Prolene in Ethicon mesh products degrades in the pelvic floor is only admissible if it is based on relevant scientific literature. *See Oglesby*, 190 F.3d at 249 (discussing *Daubert* requirements). But none of the peer reviewed papers or internal Ethicon tests to which Dr. Priddy cites actually stands for the proposition that the Prolene in Ethicon mesh products oxidizes and degrades *in vivo*.

- **Not Prolene and Speculative**. Costello's *Materials Characterization of Explanted Polypropylene Hernia Meshes*, 83B J. Biomed. Mater. Res Part B: Appl Biomater 44 (2007) analyzed only mesh manufactured by C.R. Bard, and not the Prolene at issue in this litigation. *See* Ex. I. This article is, therefore, inapposite.

- **Cannot confirm oxidation of Prolene or polypropylene.** The Clave article, encompassing 100 meshes from multiple manufacturers, expressly states that while there are many "hypotheses concerning the degradation of the PP . . . [n]one of these, particularly direct oxidation, could be confirmed in this study." Ex. J, A. Clave, *et al.*, *Polypropylene As A Reinforcement In Pelvic Surgery Is Not Inert: Comparative Analysis of 100 Explants*, 21 Int. Urogynecol. J. 261, 266 (2010).

- **Not Prolene and Not Pelvic Mesh**. Nothing in the Wood article suggests that it analyzed Prolene. *See* Ex. K, A.J. Wood, *et al.*, *Materials Characterization and Histological Analysis of Explanted Polypropylene, PTFE, and PET Hernia Meshes from an Individual Patient*, 24 J. Mater. Sci. Mater. Med. 1113 (2013). Furthermore, the article expressly states that it analyzed hernia meshes, not meshes used in the pelvic floor. *See id.*

- **Not Prolene and Antioxidants work.** The Liebert article assessed filaments prepared from polypropylene manufactured by the Hercules Company, not the Prolene at issue in this litigation. Ex. L, T. Liebert, *et al.*, *Subcutaneous Implants of PP Filaments*, 10 J. Biomed. Mater. Res. 939, 941 (1976). In addition, as even Plaintiffs' experts have admitted, the Liebert study actually found that antioxidants are effective at preventing degradation in polypropylene. *See, e.g.*, Ex. M, Guelcher 3/25/14 Dep. 73:16–74:1.

- **Not Prolene and Speculative**. There is nothing in the Williams article that suggests that it dealt with Prolene. Ex. N, D.F. Williams, 17 *Biodegradation of Surgical Polymers*, J. of Mater. Sci. 1233 (1982). In addition, Williams expressly stated that "[a]ctivation energies for the degradation of high-molecular weight polymers used in surgery vary . . . [and] generally require either heat, u.v. light, or high energy radiation . . . to proceed. It seems certain from these conditions that no such degradation should occur within the confines of the human body." *Id.* at 1236. Williams also noted that while some authors have suggested that "enzymes may be influential in degrading polymers," it was "always without proof." *Id.* at 1237.

- **Not Prolene and exposure to conditions not found in the pelvic floor.** The paper by Sternschuss and Ostergard—a paid expert for plaintiffs in pelvic mesh litigation—is merely a literature review in which the authors assert that polypropylene degrades based solely on papers that do not support the proposition that Prolene implanted in the pelvic floord degrades. *See* Ex. O, G. Sternschuss, Donald Ostergard, *et al.*, *Post-Implantation Alterations of Polypropylene in the Human*, 188 J. of Urology 27, 30-31 (2012). For instance, as discussed above, the Costello, Clave, and Williams papers simply did not address Prolene. *See supra*.

  And while the Jongebloed and Altman papers may address Prolene, they are nonetheless inapposite because they examine only sutures that had been implanted in the human eye.

Ex. P, W. Jongebloed & J. Worst, *Degradation of Polypropylene in the Human Eye: A SEM Study*, 64 Documenta Opthamologica 143 (1986); Ex. Q, W. Jongebloed, *et al.*, *Mechanical and Biochemical Effects of Man-Made Fibres and Metals in the Human Eye, A SEM Study*, 61 Documenta Opthamologica 303 (1986); Ex. R, A. Altman, *et al.*, *The Breakdown of Polypropylene in the Human Eye: Is It Clinically Significant?*, 18 Ann. Opthalmol 182 (1986). It is undisputed that all forms of polypropylene, including Prolene, oxidize when exposed to ultraviolet radiation. Thus, the fact that ocular sutures—which would necessarily be exposed to ultraviolet radiation—oxidize after implantation in the eye is neither surprising nor germane to the Prolene used in Ethicon mesh products placed in the pelvic floor.

- **Not Prolene and Speculative.** Nothing in the Chapple article stands for the proposition that Prolene is subject to degradation in the human body. *See* C. Chapple, *et al.*, *Mesh Sling in an Era of Uncertainty: Lessons Learned and the Way Forward*, 64 Euro. Uro. 525 (2013), *available at* http://www.europeanurology.com/article/S0302-2838(13)00660-X/pdf/mesh-sling-in-an-era-of-uncertainty-lessons-learned-and-the-way-forward. Rather, the article merely observes that some "articles have raised the concern that synthetic materials might not be inert when implanted in the human body," citing to the Sternschuss and Clave papers—neither of which stand for the proposition that the Prolene in Ethicon mesh products degrades *in vivo*. *See supra*.

- **Not Prolene.** The article by Miao expressly states that it did not examine any mesh composed of Prolene. Ex. S, L. Miao, *et al.*, *Physical Characteristics of Medical Textile Prostheses Designed for Hernia Repair: A Comprehensive Analysis of Select Commercial Devices*, 8 Materials 8148, 8151 (2015).

- **Not polypropylene or Prolene.** The Lundback article analyzed the performance of Santonox R in polyethylene samples. Ex. T, M. Lundback, *et al.*, 91 *Loss of Stability by Migration and Chemical Reaction of Santonox R in Branched Polyethylene Under Anaerobic and Aerobic Conditions* 1071 (2006). For this reason, it is inapplicable to polypropylene, much less the Prolene at issue in this litigation.

- **Not polypropylene or Prolene, and exposure to conditions not found in the pelvic floor.** Dr. Priddy's paper, written with Bell and others, analyzed the performance of antioxidants and acrylate rubber, not any form of polypropylene, much less the Prolene at issue in this litigation. *See* Ex. U, B. Bell, D. Priddy, *et al.*, 54 *Permanence of Polymer Stabilizers in Hostile Environments* 1605 (1994). Furthermore, the authors exposed the samples to "environments where exposure to UV radiation and strong oxidizing chemicals (e.g., swimming pools)," which is radically different than the conditions found in the human pelvic floor.

- **Not Prolene**. Nothing in the paper by Arutchelvi suggests that it addresses Prolene. *See* Ex. V, J. Arutchelvi, *et al.*, *Biodegradation of Polyethylene and Polypropylene*, 7 Indian J. of Biotechnology 9 (2008). Moreover, the Arutchelvi paper is a literature review focusing on the environmental impact of polypropylene, which the authors explain is

"recalcitrant and hence remain[s] inert to degradation and deterioration leading to [its] accumulation in the environment[.]" *Id.* at 9-13.

- **Not Prolene.** The paper by Imel and Mays—a paid expert for plaintiffs in pelvic mesh litigation—simply does not analyze Prolene. *See* Ex. W, A. Imel, *et al.*, *In vivo Oxidative Degradation of Polypropylene Pelvic Mesh*, 73 Biomaterials 131, 132 (2015).

- **Not Prolene and antioxidants work.** The article by Rene de la Rie does not address Prolene, and actually stands for the proposition that antioxidants work to retard oxidation and degradation of polymers. *See* Ex. G, *Polymer Stabilizers*, *supra*.

- **Oral presentation based on testing excluded as unreliable by this Court.** Dr. Priddy seeks to base his degradation opinion on an oral presentation delivered by Drs. Dunn, Guelcher, and Iakovlev—all paid experts for plaintiffs in pelvic mesh litigation—at a meeting of the American Institute of Chemical Engineers in November 2014. R. Dunn & S. Guelcher, *Failure Analysis of Transvaginal Mesh Products: A Biomaterials Perspective Using Materials Science Fundamentals* (2014), *available at* https://aiche.confex.com/aiche/2014/webprogram/Paper387939.html. The presentation was based on testing conducted by Drs. Guelcher and Dunn, (Ex. X, Guelcher 12/18/14 Dep. 249:7–250:21), that this Court has excluded as unreliable. *See, e.g.*, *Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at **21-22 (S.D. W. Va. May 6, 2015).

- **Does not address oxidation or degradation.** The article by Klinge and Klosterhalfen—both paid experts for plaintiffs in pelvic mesh litigation—focuses on the adoption of a classification system for hernia meshes, but does not address oxidation or degradation. Ex. Y, U. Klinge & B. Klosterhalfen, *Modified Classification of Surgical Meshes for Hernia Repair Based on the Analyses of 1,000 Explanted Meshes*, 16 Hernia 251 (2012).

- **Disproven methodology and speculative.** Dr. Priddy relies on three papers by Dr. Vladimir Iakovlev, a paid expert for plaintiffs in pelvic mesh litigation. Ex. Z, V. Iakovlev, *et al.*, *Degradation of Polypropylene* In Vivo: *A Microscopic Analysis of Meshes Explanted From Patients*, J. Biomed. Mater. Res. Part B (2015); Ex. AA, V. Iakovlev, *et al.*, *Pathology of Explanted Transvaginal Meshes*, 8 Int. J. of Med., Health, Pharm., and Biomed. Engineering 510 (2014); V. Iakovlev, *et al.*, *Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh is not Inert*, (2014), *available at https://www.researchgate.net/publication/273135551_Pathological_Findings_of_Transvaginal_Polypropylene_Slings_explanted_for_Late_Complications_Mesh_is_Not_Inert*.

  None of these papers provide reliable scientific evidence that Prolene degrades *in vivo* because they are based on the unreliable methods employed by Dr. Iakovlev, whose degradation "bark" hypothesis has been disproven. *See* Mem. in Supp. of Mot. to Exclude Dr. Iakovlev, *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, (filed concurrently with this motion). Moreover, none of these papers incorporated analytical chemistry testing to determine if the mesh lost molecular weight, which Plaintiffs' other materials scientists agree is necessary to establish degradation. *See* Ex. E,

Mays 3/2/16 Dep. 79:3-80:12 ("Q. But, Doctor, for oxidative degradation to occur, there must be loss of molecular weight, correct? A. Yes, when oxidative degradation occurs, there is degradation of molecular weight."); *see also* Ex. BB, Jordi 10/30/13 Dep. 173:25–174:8 (admitting that test results showing no loss of molecular weight suggests that there is no degradation of polypropylene).

B. Dr. Priddy relies on undpublished Ethicon documents that do not support his opinion.

Dr. Priddy also seeks to support his opinion that Prolene degrades *in vivo* by referring to certain unpublished Ethicon documents regarding Prolene sutures. Ex. F, Priddy Report at 13-14 nn. 34 & 35. But these internal documents do not support Dr. Priddy's degradation opinions.

Dr. Priddy points to Ethicon's 1987 Prolene suture test as evidence that Prolene is subject to oxidative degradation. Ex. F, Priddy Report at 14 n. 35; *see also* Ex. CC, IR Microscopy of Explanted Prolene (Sept. 30, 1987), ETH.MESH.12831391–1404. But the 1987 suture test does not support Dr. Priddy's opinion that Prolene degrades *in vivo*, because it did not report a change in molecular weight in the sutures, which other experts for Plaintiffs in this litigation have acknowledged is a fundamental component of oxidative degradation. *See* Ex. E, Mays 3/2/16 Dep. 79:3-80:12; Ex. BB, Jordi 10/30/13 Dep. 173:25–174:8. Nor did the test make any findings that the sutures' mechanical properties—such as elongation and tensile strength—diminished.

Dr. Priddy cites numerous Ethicon's "canine explant studies" as proof that Prolene oxidizes and degrades *in vivo*, but all of those documents are part of Ethicon's seven-year dog study of Prolene sutures. Ex. F, Priddy Report at 13 n.34.[8] Moreover, Dr. Priddy's reliance on the dog study is misplaced because—as Plaintiffs' experts concede—it reported no significant loss of molecular weight. *See, e.g.*, Ex. E, Mays 3/2/16 Dep. 151:4-14 (admitting the study reported no significant loss of molecular weight and no "molecular weight degradation"). The

[8] Dr. Priddy cites Ex. DD, ETH.MESH.12729337; Ex. EE, ETH.MESH.07690752; Ex. FF, ETH.MESH.05453719; Ex. GG, ETH.MESH.11336184; Ex. HH, ETH.MESH.11336071; Ex. II, ETH.MESH.11336165; Ex. JJ, ETH.MESH.09888187; Ex. KK, ETH.MESH.11336181.

study also indicates that the sutures were plasticized *in vivo*, which Plaintiffs' other materials scientists concede would actually improve the toughness of the suture. *Id.* at 154:2-13.[9]

Ultimately, neither Dr. Priddy's testing nor any of the articles or internal Ethicon documents to which Dr. Priddy cites supports his opinion that the Prolene in Ethicon mesh products degrades in the human body. Accordingly, the Court should exclude his opinions as unreliable. *See Nease*, 848 F.3d at 234.

IV. The Court Should Preclude Dr. Priddy From Testifying About Issues Beyond His Qualifications and Which Do Not Assist the Trier of Fact.

A. Dr. Priddy's Opinions Regarding Ethicon's Alleged Knowledge, State of Mind, and Corporate Conduct Do Not Help the Jury.

Dr. Priddy offers several opinions regarding Ethicon's alleged knowledge regarding the oxidation and degradation of polypropylene. *See, e.g.*, Ex. F, Priddy Report at 4, 14. But this Court has repeatedly held that a corporate defendant's "knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *See, e.g.*, *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013). The Court should exclude this testimony for this reason alone.

In addition, Dr. Priddy is not qualified to opine about Ethicon's corporate knowledge and conduct. Dr. Priddy is a chemical engineer. His resume does "not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and

[9] Although Dr. Priddy did not concede that the dog study data show improved toughness, he acknowledged that a plot of the dog study data on a stress-strain showed an increase of the area under the curve, which is how toughness is defined. Ex. D, Priddy 3/8/16 Dep. 140:16-22; 142:18-143:24. Notably, Dr. Priddy failed to identify a scientific basis for his position that the plot of the dog study data did not satisfy the definition of increased toughness, instead saying that "something is wrong" because it "doesn't look right." *See id.* at 140:16-144:22.

influenced by shareholders or public opinion." *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at 9 (E.D. Pa. June 20, 2000). Dr. Priddy is thus unqualified to offer any opinions concerning Ethicon's corporate conduct.

B. Dr. Priddy is Unqualified to Opine that the Alleged Degradation of Prolene in Ethicon Mesh Products Causes Clinical Complications.

Dr. Priddy seeks to inform the jury that "Ethicon's failure to [test mesh to determine whether it would withstand permanent implantation] . . . jeopardized the health of the women receiving their products," Ex. F, Priddy Report at 14, but any opinion regarding clinical complications is beyond the scope of Dr. Priddy's qualifications.

Dr. Priddy is not a medical doctor. *See* Ex. D, Priddy 3/8/16 Dep. 20:9–14. Thus, he lacks the qualifications necessary to offer opinions regarding clinical complications. Indeed, Dr. Priddy acknowledged that "since I'm not a medical doctor, I can't equate the clinical" significance of his degradation opinions. *Id.* at 123:9–12. For this reason, the Court should exclude his testimony on these issues. *See* Mem. Op. and Order (*Daubert* Motion re: Jimmy W. Mays, Ph.D.), No. 2:12-md-02327, at 6 (S.D. W. Va. Aug. 25, 2016) [ECF # 2646] (precluding materials scientist from offering opinions regarding complications in pelvic mesh litigation); Mem. Op. and Order (*Daubert* Motion re: Scott A. Guelcher, Ph.D.), No. 2:12-md-02327, at 6 (S.D. W. Va. Aug. 31, 2016) [ECF # 2698]. The Court's ruling here should be no different.

CONCLUSION

For the foregoing reasons, Ethicon requests that the Court exclude the opinion testimony of Dr. Priddy, and grant such other and further relief as the Court deems proper under the circumstances.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 4 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I hereby certify that on April 13, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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